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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1067 Rev. 02

Manufacturer: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

Product: **Implantable Cardiac Monitoring and Recording Systems with a conditional intended use in a MRI environment**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713156134

Valid from: 2019-10-21
Valid until: 2023-11-07

Date, 2019-10-21

Stefan Preiß
Head of Certification/Notified Body

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EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1067 Rev. 02

Model(s): **see below**

Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Europe Sàrl
Route du Molliau 31, Case Postale, 1131 Tolochenaz, SWITZERLAND

Medtronic Singapore Operations Pte. Ltd.
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056, SINGAPORE

Design Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Parameters:

Clinical MRI systems with:
- a static magnetic field of 1,5T or 3,0T
- a max. spatial gradient of 25T/m
- a max. gradient slew rate performance per axis <= 200T/m/s
- a whole-body SAR <= 4,0W/kg
- a head SAR <= 3,2W/kg

Product: **Implantable Cardiac Monitoring and Recording Systems (Implant)**

Test Report No.: 713029780

Model:	**Model No:**
Reveal LINQ	LNQ11

Test Report No.: 713052876

Model:	**Model No:**
Reveal LINQ insertion tools	LNQTOOL

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1067 Rev. 02

Product: Application Software (external)

Test Report No.: 713030403

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW026	2090 and 29901	Reveal LINQ

Test Report No.: 713059729 / 713156134

Model:	Model No:	Implants to be programmed:
Reveal LINQ Mobile Manager App	MSW001	Reveal LINQ

Test Report No.: 713082131 / 713156134

Model:	Model No:	Implants to be programmed:
Reveal LINQ Mobile Manager App	MSW002	Reveal LINQ LINQ II

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Manufacturer: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative: Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

Product: **Implantable Pacemaker Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713127272

Valid from: 2018-09-30
Valid until: 2023-09-29

Date, 2018-09-19

Stefan Preiß

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Model(s): **see below**

Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Puerto Rico Operations Co., Juncos
Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR 00777, USA

Medtronic Europe Sàrl
Route du Molliau 31, Case Postale, 1131 Tolochenaz, SWITZERLAND

Medtronic Singapore Operations Pte. Ltd.
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056, SINGAPORE

Design Facility(ies): Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Parameters: ./.

Implantable Pacemaker System: SureScan™

Product: **Implantable Pacemaker**

Test Report No.: 71350692

Model:	**Model No:**	**Variant:**
Advisa DR MRI™ SureScan™	A3DR01	MR Conditional

Test Report No.: 71366167

Model:	**Model No:**	**Variant:**
Ensura DR MRI™ SureScan™	EN1DR01	MR Conditional

Test Report No.: 713039269

Model:	**Model No:**	**Variant:**
Advisa SR MRI™ SureScan™	A3SR01	MR Conditional
Ensura SR MRI™ SureScan™	EN1SR01	MR Conditional

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(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: Application Software (external)

Test Report No.: 71338901

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW005	2090	EnRhythm EMDR01

Test Report No.: 71351141

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090	Advisa A3DR01

Test Report No.: 71368678

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090	Ensura EN1DR01

Test Report No.: 713006624

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW018	2090	RevoMRI (US only)

Test Report No.: 713039234

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090 29901	Advisa SR MRI SureScan A3SR01 Ensura SR MRI SureScan EN1SR01

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(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: **Implantable Pacemakers**

Test Report No.: 713095776

Model:	**Model No:**	**Variant:**
Percepta™ Quad CRT-P MRI SureScan™	W4TR04	MR Conditional
Serena™ Quad CRT-P MRI SureScan™	W4TR05	MR Conditional
Solara™ Quad CRT-P MRI SureScan™	W4TR06	MR Conditional
Percepta™ CRT-P MRI SureScan™	W1TR04	MR Conditional
Serena™ CRT-P MRI SureScan™	W1TR05	MR Conditional
Solara™ CRT-P MRI SureScan™	W1TR06	MR Conditional

Product: **Application Software (external)**

Test Report No.: 713095780

Model:	**Model No:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	SW040	2090 29901	Percepta™ Quad CRT-P MRI SureScan™ W4TR04 Serena™ Quad CRT-P MRI SureScan™ W4TR05 Solara™ Quad CRT-P MRI SureScan™ W4TR06 Percepta™ CRT-P MRI SureScan™ W1TR04 Serena™ CRT-P MRI SureScan™ W1TR05 Solara™ CRT-P MRI SureScan™ W1TR06

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(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: Application Software

Test Report No.: 713095771

Model:	**Model No:**	**for Programmer:**	**Implants to be programmed:**
Azure / Astra Application Software	SW030	2090 29901	Azure™ XT DR MRI SureScan™ W2DR01 Azure™ S DR MRI SureScan™ W3DR01 Azure™ XT SR MRI SureScan™ W2SR01 Azure™ S SR MRI SureScan™ W3SR01 Astra™ XT DR MRI SureScan™ X2DR01 Astra™ S DR MRI SureScan™ X3DR01 Astra™ XT SR MRI SureScan™ X2SR01 Astra™ S SR MRI SureScan™ X3SR01

Product: **Implantable Pacemakers**

Test Report No.: 713095773

Model:	**Model No:**	**Variant:**
Azure™ XT DR MRI SureScan™	W2DR01	MR Conditional
Azure™ S DR MRI SureScan™	W3DR01	MR Conditional
Azure™ XT SR MRI SureScan™	W2SR01	MR Conditional
Azure™ S SR MRI SureScan™	W3SR01	MR Conditional
Astra™ XT DR MRI SureScan™	X2DR01	MR Conditional
Astra™ S DR MRI SureScan™	X3DR01	MR Conditional
Astra™ XT SR MRI SureScan™	X2SR01	MR Conditional
Astra™ S SR MRI SureScan™	X3SR01	MR Conditional

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(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: **Implantable Pacemakers**

Test Report No.: 713105247

Model:	**Model No:**	**Variant:**
Attesta™ DR MRI SureScan™	ATDR01	MR Conditional
Attesta™ L DR MRI SureScan™	ATDRL1	MR Conditional
Attesta™ S DR MRI SureScan™	ATDRS1	MR Conditional
Attesta™ SR MRI SureScan™	ATSR01	MR Conditional
Sphera™ DR MRI SureScan™	SPDR01	MR Conditional
Sphera™ L DR MRI SureScan™	SPDRL1	MR Conditional
Sphera™ SR MRI SureScan™	SPSR01	MR Conditional

Product: **Application Software (external)**

Test Report No.: 713105248

Model:	**Model No:**	**For Programmer:**	**Implants to be programmed**
Application Software	SW043	2090 29901	Attesta™ DR MRI SureScan™ ATDR01 Attesta™ L DR MRI SureScan™ ATDRL1 Attesta™ S DR MRI SureScan™ ATDRS1 Attesta™ SR MRI SureScan™ ATSR01 Sphera™ DR MRI SureScan™ SPDR01 Sphera™ L DR MRI SureScan™ SPDRL1 Sphera™ SR MRI SureScan™ SPSR01

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(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 00

Product: Application Software (external)

Test Report No.: 713127914

Model:	**Model No:**	**External Device Manager System supported:**
CareLink SmartSync Azure Astra App	D00U003	CareLink SmartSync Device Manager Patient Connector 24967

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Number: 2258950CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands
SRN ID.: NL-MF-000010926

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2007317CN

Additional certificate: 2258950TD01/2258950TD02

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Principal Certification Manager

First Issued: **1 July 2022** Date: **21 October 2022** Expiry date**: 1 July 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2258950CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Class III
Crystalline Crystalline ActFix Crystalline ActFix MRI SureScan
Q80 DR MRI SureScan™ Q70 DR MRI SureScan™ G70 DR MRI SureScan™ Q50 DR MRI SureScan™ G20 SR MRI SureScan™ Q20 SR MRI SureScan™ Vitatron® VSF21 Application Software, VSF21, For Programmer: 2090 and 29901

First Issued: **1 July 2022** Date: **21 October 2022** Expiry date**: 1 July 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

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2184-4

Number: 2258950CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	01-07-2022	2007317CN91	First Issue
1	19-07-2022	2007317CN92	Revised
2	21-10-2022	2007317CN93	Revised

First Issued: **1 July 2022** Date: **21 October 2022** Expiry date**: 1 July 2027**

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2184-4

Number: 2258950TD02

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands
SRN ID.: NL-MF-000010926

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2007317CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Principal Certification Manager

First Issued: **19 July 2022** Date: **21 October 2022** Expiry date**: 1 July 2027**

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Number: 2258950TD02

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

This certificate covers the following device(s) / groups of device(s):

Class III	
Basic UDI-DI: 0763000B00005427P Q80 DR MRI SureScan™, Q80A2, Dual Chamber (J01010302, dual-chamber implantable pacemakers with rate modulation sensor (DR)) Q70 DR MRI SureScan™, Q70A2, Dual Chamber (J01010302, dual-chamber implantable pacemakers with rate modulation sensor (DR)) G70 DR MRI SureScan™, G70A2, Dual Chamber (J01010302, dual-chamber implantable pacemakers with rate modulation sensor (DR)) Q50 DR MRI SureScan™, Q50A2, Dual Chamber (J01010302, dual-chamber implantable pacemakers with rate modulation sensor (DR)) G20 SR MRI SureScan™, G20A2, Single Chamber (J01010102, single-chamber implantable pacemakers with rate modulation sensor (SR)) Q20 SR MRI SureScan™, Q20A2, Single Chamber (J01010102, single-chamber implantable pacemakers with rate modulation sensor (SR)) **Basic UDI-DI: 0763000B00005437R** Vitatron® VSF21 Application Software, VSF21, For Programmer: 2090 and 29901 (J01900282, programming units for implantable cardiac devices - software)	Intended Purpose: Pacemakers are intended for long-term use to monitor and regulate the patient's heart rate. Pacemakers sense intrinsic electrical activity through lead electrodes, analyze heart rhythms based on programmed detection parameters, and deliver pacing pulses to treat bradyarrhythmias. The software is intended to provide information which is used to make decisions with diagnostic or therapeutic devices.

First Issued: **19 July 2022** Date: **21 October 2022** Expiry date**: 1 July 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

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T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2258950TD02

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	19-07-2022	2007317CN92	First Issue
1	21-10-2022	2007317CN93	Revision
2			

First Issued: **19 July 2022** Date: **21 October 2022** Expiry date**: 1 July 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1192 Rev. 01

Manufacturer: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative: Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

Product: **Implantable Cardioverter / Defibrillator Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713134811

Valid from: 2019-03-31
Valid until: 2024-03-30

Date, 2019-02-26

Stefan Preiß

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EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1192 Rev. 01

Model(s): **see below**

Facility(ies):

Medtronic Europe Sàrl
Route du Molliau 31, Case Postale, 1131 Tolochenaz,
SWITZERLAND

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Puerto Rico Operations Co., Juncos
Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR
00777, USA

Parameters: ./.

Design Facility(ies)

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Product: **Implantable Defibrillator Systems with a conditional intended use in a MRI environment**

Test Report No.: 713036156/ 713066030/ 713070151

Model:	Model No:	Variant:
Evera MRI™ XT DR SureScan™	DDMB2D4	MR Conditional
Evera MRI™ S DR SureScan™	DDMC3D4	MR Conditional
Evera MRI™ XT VR SureScan™	DVMB2D4	MR Conditional
Evera MRI™ S VR SureScan™	DVMC3D4	MR Conditional
Visia AF MRI™ XT VR SureScan™	DVFB2D4	MR Conditional
Visia AF MRI™ S VR SureScan™	DVFC3D4	MR Conditional
Claria MRI™ CRT-D SureScan™	DTMA2D4	MR Conditional
Claria MRI™ Quad CRT-D SureScan™	DTMA2QQ	MR Conditional
Amplia MRI™ CRT-D SureScan™	DTMB2D4	MR Conditional
Amplia MRI™ Quad CRT-D SureScan™	DTMB2QQ	MR Conditional
Compia MRI™ CRT-D SureScan™	DTMC2D4	MR Conditional
Compia MRI™ Quad CRT-D SureScan™	DTMC2QQ	MR Conditional

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1192 Rev. 01

Product: Application Software (external)

Test Report No.: 713035259/ 713043072/ 713066195/ 713070300

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW033	2090 29901	Evera MRI™ XT DR SureScan™ DDMB2D4 Evera MRI™ S DR SureScan™ DDMC3D4 Evera MRI™ XT VR SureScan™ DVMB2D4 Evera MRI™ S VR SureScan™ DVMC3D4
Application Software (external)	SW035	2090 29901	Visia AF MRI™ XT VR SureScan™ DVFB2D4 Visia AF MRI™ S VR SureScan™ DVFC3D4
Application Software (external)	SW034	2090 29901	Claria MRI™ CRT-D SureScan™ DTMA2D4 Claria MRI™ Quad CRT-D SureScan™ DTMA2QQ Amplia MRI™ CRT-D SureScan™ DTMB2D4 Amplia MRI™ Quad CRT-D SureScan™ DTMB2QQ Compia MRI™ CRT-D SureScan™ DTMC2D4 Compia MRI™ Quad CRT-D SureScan™ DTMC2QQ

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1192 Rev. 01

Product: **Implantable Defibrillator Systems with a conditional intended use in a MRI environment**

Test Report No.: 713082148

Model:	Model No:	Variant:
Claria MRI™ CRT-D SureScan™	DTMA2D1	MR Conditional
Claria MRI™ Quad CRT-D SureScan™	DTMA2Q1	MR Conditional
Amplia MRI™ CRT-D SureScan™	DTMB2D1	MR Conditional
Amplia MRI™ Quad CRT-D SureScan™	DTMB2Q1	MR Conditional
Compia MRI™ CRT-D SureScan™	DTMC2D1	MR Conditional

Test Report No.: 713081046

Model:	Model No:	Variant:
Visia AF MRI™ XT VR SureScan™	DVFB2D1	MR Conditional
Visia AF MRI™ S VR SureScan™	DVFC3D1	MR Conditional
Evera MRI™ XT DR SureScan™	DDMB2D1	MR Conditional
Evera MRI™ S DR SureScan™	DDMC3D1	MR Conditional
Evera MRI™ XT VR SureScan™	DVMB2D1	MR Conditional
Evera MRI™ S VR SureScan™	DVMC3D1	MR Conditional

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1192 Rev. 01

Product: **Application Software (external)**

Test Report No.: 713083279

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW033	2090 29901	Evera MRI™ XT DR SureScan™ DDMB2D1 Evera MRI™ S DR SureScan™ DDMC3D1 Evera MRI™ XT VR SureScan™ DVMB2D1 Evera MRI™ S VR SureScan™ DVMC3D1
Application Software (external)	SW035	2090 29901	Visia AF MRI™ XT VR SureScan™ DVFB2D1 Visia AF MRI™ S VR SureScan™ DVFC3D1
Application Software (external)	SW034	2090 29901	Claria MRI™ CRT-D SureScan™ DTMA2D1 Claria MRI™ Quad CRT-D SureScan™ DTMA2Q1 Amplia MRI™ CRT-D SureScan™ DTMB2D1 Amplia MRI™ Quad CRT-D SureScan™ DTMB2Q1 Compia MRI™ CRT-D SureScan™ DTMC2D1

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1192 Rev. 01

Test Report No.: 713118724

Model:	**Model No:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	SW033	2090 29901	Primo MRI™ DR SureScan™ DDMD3D4 Primo MRI™ DR SureScan™ DDMD3D1 Primo MRI™ VR SureScan™ DVMD3D4 Primo MRI™ VR SureScan™ DVMD3D1 Mirro MRI™ DR SureScan™ DDME3D4 Mirro MRI™ DR SureScan™ DDME3D1 Mirro MRI™ VR SureScan™ DVME3D4 Mirro MRI™ VR SureScan™ DVME3D1

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 0978 Rev. 01

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product: **Implantable Pacemaker Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713158635

Valid from: 2020-04-09
Valid until: 2024-05-26

Date, 2020-03-23

Christoph Dicks
Head of Certification/Notified Body

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 0978 Rev. 01

Model(s): **see below**

Product: **Implantable Pacemaker Systems**

Test Report No.: 713053357

Model:	**Model no.:**
Micra	MC1VR01

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EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE08

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway NE
Minneapolis MN 55432
United States Of America

For the product / product category

Steroid eluting, bipolar, active, transvenous pacing lead

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 14 June 2004

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 14 June 2004
Reissued: 1 July 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2007841TE08

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Steroid eluting, bipolar, active, transvenous pacing lead

Issued to:

Medtronic Inc.
710 Medtronic Parkway NE
Minneapolis MN 55432
United States Of America

This certificate covers the following product(s):

CapSureFix™ Novus 4076
CapSureFix Novus MRI™ SureScan™ 4076

The product is designed in the facility:

Medtronic, Inc., 8200 Coral Sea Street, Mounds View, MN 55112, USA

EC Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Initial date: 14 June 2004

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE22

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway
Minneapolis MN 55432
United States Of America

For the product / product category

Steroid eluting, quadripolar electrode, transvenous, over-the-wire delivered, IS4 compatible, cardiac vein pacing leads

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 1 January 2013

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 January 2024
Issued for the first time: 1 January 2013
Reissued: 1 January 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2007841TE22

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Steroid eluting, quadripolar electrode, transvenous, over-the-wire delivered, IS4 compatible, cardiac vein pacing leads

Issued to:

Medtronic Inc.
710 Medtronic Parkway
Minneapolis MN 55432
United States Of America

This certificate covers the following product(s):

Attain Performa™ 4298
Attain Performa™ Straight 4398
Attain Performa™ S 4598
Attain Performa™ MRI SureScan™ 4298
Attain Performa™ Straight MRI SureScan™ 4398
Attain Performa™ S MRI SureScan™ 4598

Medtronic, Inc., 8200 Coral Sea Street, Mounds View, MN 55112, USA (Design)
Medtronic Puerto Rico Operations Co., Villalba
Rd. 149, Km 56.3, Call Box 6001, Villalba PR00766, USA

EC Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Initial date: 1 January 2013

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE29

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

For the product / product category

Leads for Tachy IPGs/ ICDs and their auxiliary components

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 April 2001
Addendum, initially dated 30 April 2018

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 30 March 2024
Issued for the first time: 30 April 2018
Reissued: 30 March 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2007841TE29

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Leads for Tachy IPGs/ ICDs and their auxiliary components

Issued to:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

This certificate covers the following product(s):

Sprint Quattro Secure MRI TM SureScan ™ models 6947, 6947M
Sprint Quattro Secure S MRI™ SureScan™ models 6935, 6935M
Sprint QuattroTM MRI SureScan TM 6946M

Initial date: 30 April 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1413 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039709 1413 Rev. 00

Report No.: 713233169, 713228520

Valid from: 2022-08-29
Valid until: 2027-08-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-08-29

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TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1413 Rev. 00

Classification:	III
Device Group:	J019002 - IMPLANTABLE CARDIAC DEVICES PROGRAMMERS AND ACCESSORIES
Basic UDI-DI:	0763000B00010006M
Intended Purpose:	The Application Software (external) is intended to work with an external instrument. It provides diagnostic information which enables the clinician to choose from an array of available therapies and adjust them according to patient needs.
Device(s):	Application Software (external) Model No.: SW016, SW035, SW033

Classification:	III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	0763000B00009958Y
Intended Purpose:	Implantable cardioverter defibrillators (ICDs) are intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver antitachycardia pacing therapies, cardioversion, and defibrillation to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrhythmias with pacing therapies.
Device(s):	Evera™ XT VR DVBB2D1 Evera™ XT VR DVBB2D4 Evera™ S VR DVBC3D1 Evera™ S VR DVBC3D4 Visia AF™ XT VR DVAB2D1 Visia AF™ XT VR DVAB2D4 Visia AF™ S VR DVAC3D1 Visia AF™ S VR DVAC3D4 Evera MRI™ XT VR SureScan™ DVMB2D1 Evera MRI™ XT VR SureScan™ DVMB2D4 Evera MRI™ S VR SureScan™ DVMC3D1 Evera MRI™ S VR SureScan™ DVMC3D4 Visia AF MRI™ XT VR SureScan™ DVFB2D1 Visia AF MRI™ XT VR SureScan™ DVFB2D4 Visia AF MRI™ S VR SureScan™ DVFC3D1 Visia AF MRI™ S VR SureScan™ DVFC3D4

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BS-MDR-099

TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1413 Rev. 00

Classification:	III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	0763000B00009958Y
Intended Purpose:	Implantable cardioverter defibrillators (ICDs) are intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver antitachycardia pacing therapies, cardioversion, and defibrillation to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrhythmias with pacing therapies.
Device(s):	Primo MRI™ VR SureScan™ DVMD3D1 Primo MRI™ VR SureScan™DVMD3D4 Mirro MRI™ VR SureScan™ DVME3D1 Mirro MRI™ VR SureScan™ DVME3D4

Classification:	III
Device Group:	J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS
Basic UDI-DI:	0763000B00009958Y
Intended Purpose:	Implantable cardioverter defibrillators (ICDs) are intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver antitachycardia pacing therapies, cardioversion, and defibrillation to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrhythmias with pacing therapies.
Device(s):	Evera™ XT DR DDBB2D1 Evera ™ XT DR DDBB2D4 Evera ™ S DR DDBC3D1 Evera ™ S DR DDBC3D4 Evera MRI™ XT DR SureScan™ DDMB2D1 Evera MRI™ XT DR SureScan™ DDMB2D4 Evera MRI™ S DR SureScan™ DDMC3D1 Evera MRI™ S DR SureScan™ DDMC3D4 Primo MRI™ DR SureScan™ DDMD3D1 Primo MRI™ DR SureScan™ DDMD3D4 Mirro MRI™ DR SureScan™ DDME3D1 Mirro MRI™ DR SureScan™ DDME3D4

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(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1413 Rev. 00

Classification:	III
Device Group:	J010503 - IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	0763000B000099692
Intended Purpose:	Cardiac resynchronization therapy defibrillators are implantable devices intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes and analyze heart rhythms based on programmed detection parameters. The devices deliver pacing therapies to treat bradyarrhythmias and heart failure, and provide antitachycardia pacing, cardioversion and defibrillation therapies to treat life-threatening ventricular tachyarrhythmias.
Device(s):	Viva™ XT CRT-D DTBA2D1 Viva™ XT CRT-D DTBA2D4 Viva™ QUAD XT CRT-D DTBA2Q1 Viva™ QUAD XT CRT-D DTBA2QQ Viva™ S CRT-D DTBB2D1 Viva™ S CRT-D DTBB2D4 Viva™ QUAD S CRT-D DTBB2Q1 Viva™ QUAD S CRT-D DTBB2QQ Brava™ CRT-D DTBC2D1 Brava™ CRT-D DTBC2D4 Brava™ QUAD CRT-D DTBC2Q1 Brava™ QUAD CRT-D DTBC2QQ
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 039709 1393 Rev. 01

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G12 039709 1393 Rev. 01

Report No.: 713269057

Preceding Certificate No.: G12 039709 1393 Rev. 00

Valid from: 2022-08-29
Valid until: 2027-04-10

Date of Initial Issuance: 2022-04-11

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-08-29

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EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 039709 1393 Rev. 01

Classification:	III
Device Group:	J019002 - IMPLANTABLE CARDIAC DEVICES PROGRAMMERS AND ACCESSORIES
Intended Purpose:	.
Classification:	III
Device Group:	J010103 - IMPLANTABLE DUAL CHAMBER PACEMAKERS
Intended Purpose:	-
Classification:	III
Device Group:	J010101 - IMPLANTABLE SINGLE CHAMBER PACEMAKERS
Intended Purpose:	-
Classification:	III
Device Group:	J010102 - IMPLANTABLE SINGLE LEAD PACEMAKERS
Intended Purpose:	-
Classification:	III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Intended Purpose:	-
Classification:	III
Device Group:	J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS
Intended Purpose:	-
Classification:	III
Device Group:	J010503 - IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History:

Rev.	Dated	Report
00	2022-04-11	713220016, 713220285

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